REMARKS

Claims 1-13 and 25 are withdrawn from consideration in response to a restriction requirement. Claims 20 and 21 have been cancelled. New claims 30 and 31 have been introduced. Claims 14-16, 22-24 and 26-29 have been amended. Support for the amendments is found in the specification as filed. Consequently, no new matter has been introduced by the amendments.

Applicant thanks the Examiner for the telephonic interview on October 5, 2007, wherein the pending claims and cited references were discussed.

Rejection of claims 14, 15, 19-24 and 26-29 under 35 U.S.C. § 103(a)

Claims 14, 15, 19-24 and 26-29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hutchins et al. (U.S. 6,676,659) in view of Richardson (U.S. Pub. No. 2003/0078473), further in view of certain Boston Scientific documents. The Boston Scientific documents appended to the Office Action consist of: 1) a 2001 Price list and Ordering Information brochure for Products for Endoscopy; 2) an October 19, 2001 510(k) Summary for an Autotome™ Rx sphincterotome; and 3) 2003 Boston Scientific marketing literature for the Autotome™ Rx Cannulating Sphincterotomes. Applicant respectfully disagrees and traverses the rejection.

Applicant respectfully submits that neither Hutchins et al., Richardson, nor the Boston Scientific documents, either alone or in combination, teach or suggest a catheter comprising two or more lumens, at least one of which is sized to receive a 0.035 inch guidewire, a distal tip having a tapered portion of "approximately 3 millimeters or less" (claim 14) or "within the range of 1.5 mm to 4.5 mm" (claim 26), and a distal terminus with an outer diameter of "less than approximately .063 inch" (claim 14) or "within the range of 0.055 inch-0.063 inch" (claim 26). Specifically, Hutchins et al. does not disclose a tapered tip, Applicant's claimed taper length, or Applicant's claimed outer diameter for the distal terminus. Richardson discloses a tapered tip and a broad range for the taper length, but does not recognize the desirability of, or teach one of skill how to design, a 0.035 guidewire-compatible distal tip having Applicant's claimed taper

length and distal terminus outer diameter. The Office Action states that Boston Scientific discloses a sphincterotome having a tip outer diameter of 3.5 Fr or 0.046 inches. However, this assertion is made in relation to the 2001 Tapertome™ Single-Use Sphincterotome, which does not have a lumen sized to receive a 0.035 inch guidewire. The largest guidewire that can be accommodated by the Tapertome is .025 inch. Moreover, the Tapertome's .046 inch tip outer diameter is outside the distal terminus range of claim 26 (0.055-0.063 inch).

The 510(k) Summary discloses an Autotome™ Rx triple lumen sphincterotome that is specified as being capable of accommodating a 0.035 inch guidewire. However, the 510(k) Summary fails to disclose an outer diameter for the distal terminus of the device, whether the tip is tapered or blunt, and if tapered, the taper length. Applicant respectfully disagrees with the Examiner's assertion that the 510(k) Summary discloses a sphincterotome having a "tip outer diameter of 4.9 Fr or 0.064 inches." This is simply not found in the 510(k) document. Applicant respectfully submits that the 510(k) summary fails to teach or suggest Applicant's claimed catheter. Moreover, while the 510(k) Summary bears the date of October 19, 2001, there is no evidence in the record to prove that the 510(k) Summary was available to the public as of this date.

The 2003 Boston Scientific marketing literature for the Autotome™ Rx Cannulating Sphincterotomes is not properly citable as prior art in relation to the subject application, which claims priority to Provisional Application No. 60/423,311 filed on November 1, 2002.

The Examiner asserts that the subject matter of claims 23-24, 26, and 29 would have been obvious on the grounds that "where the general conditions of a claim are disclosed in the prior art, discovering the optimal or workable ranges involves only routine skill in the art." Office Action, page 5. Applicant rebuts this assertion with the Declaration of Harold Mark Aznoian. In this declaration, Mr. Aznoian presents facts and opinions concerning the scope and content of the prior art and competitive marketplace for biliary catheters. Mr. Aznoian also ascertains the differences between the claimed invention and the prior art; and supplies facts to support the conclusion that the design and reduction to practice of the claimed catheters required expertise beyond the level of routine skill in the art.

Claims 15, 19 and 22-24 depend, directly or indirectly, from claim 14. For the same reasons as stated above for claim 14, Applicant respectfully submits that claims 15, 19 and 22-24 are in condition for allowance. Claims 27-29 depend, directly or indirectly, from claim 26. For the same reasons as stated above for claim 26, Applicant respectfully submits that claims 27-29 are also in condition for allowance.

Rejection of claims 17 and 18 under 35 U.S.C. § 103(a)

Claims 17 and 18 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Hutchins et al. in view of Richardson, further in view of Boston Scientific, and further in view of Sadamasa (U.S. 6,017,339).

Claims 17 and 18 depend from independent claim 14. For the same reasons as stated above for claim 14, Applicant respectfully submits that claims 17 and 18 are in condition for allowance.

CONCLUSION

Applicant's discussion of particular positions of the Examiner does not constitute a concession with respect to any positions that are not expressly contested by the Applicant. Applicant's emphasis of particular reasons why the claims are patentable does not imply that there are not other sufficient reasons why the claims are patentable, nor does it imply the claims were not allowable in their original form.

Applicant respectfully submits that all pending claims are in condition for allowance and request withdrawal of the current rejections. If the Examiner believes a telephonic interview would expedite the prosecution of the present application, the Examiner is encouraged to contact Applicant's Attorney at the number below.

Dated: November 30, 2007

Respectfully submitted,

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